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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte KEI ROGER AOKI, MICHAEL W. GRAYSTON,
STEVEN R. CARLSON, and JUDITH M. LEON

Appeal 2009-010021
Application 10/726,904
Technology Center 1600

Before TONI R. SCHEINER, DONALD E. ADAMS, and ERIC GRIMES,
Administrative Patent Judges.

SCHEINER, *Administrative Patent Judge*.

DECISION ON REQUEST FOR REHEARING

Appellants request reconsideration of the Decision on Appeal entered May 21, 2010, which affirmed the rejection of claims 1, 2, 4, 5, 29, 47, and 63 on the ground of obviousness.

We have reconsidered our Decision in light of Appellants' position, and have modified our Decision only to the extent that we designate our affirmance a new ground of rejection.

BACKGROUND

The claimed invention is directed to a method for treating strabismus by administering a therapeutically effective amount of the neurotoxic component of a botulinum toxin to a patient, wherein the neurotoxic component has a molecular weight of about 150 kilodaltons (*see* claim 1).

The Examiner rejected the claims as obvious over the combined teachings of Balkan[1] or Han[2] in view of Kohl,[3] Tse,[4] and Aoki '915.[5] The Examiner took the position that the Han, Kohl and Aoki '915 references were available as prior art against the claimed invention because the claims in the present application were not enabled as of the December 28, 1993 filing date of abandoned parent application 08/173,996 (Ans. 4-8), largely on the basis of the teachings of the Schantz reference.[6]

We determined that the Examiner's findings and rationale regarding enablement of the claimed method were not supported by the evidence, and

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[1] Robert J. Balkan & Taylor Poole, *A Five-Year Analysis of Botulinum Toxin Type A Injections: Some Unusual Features*, 23 ANN OPHTHALMOL 326-333 (1991).

[2] Sueng Han Han et al., *Effect of Botulinum Toxin A Chemodenervation in Sensory Strabismus*, 38 JOURNAL OF PEDIATRIC OPHTHALMOLOGY AND STRABISMUS 68-71 (2001).

[3] A. Kohl et al., *Comparison of the effect of botulinum toxin A (Botox ®) with the highly-purified neurotoxin (NT 201) in the extensor digitorum brevis muscle test*, 15(Suppl 3) MOV DISORD 165 (2000).

[4] Chun K. Tse et al., *Preparation and Characterisation of Homogeneous Neurotoxin Type A from Clostridium botulinum*, 122 EUR. J. BIOCHEM. 493-500 (1982).

[5] US 6,113,915, issued Sep. 5, 2000 to Aoki et al.

[6] Edward J. Schantz & Eric A. Johnson, *Properties and Use of Botulinum Toxin and Other Microbial Neurotoxins in Medicine*, 56 MICROBIOLOGICAL REVIEWS 80-99 (1992).

therefore, the Han, Kohl and Aoki '915 references were not available as prior art (*see* Decision 8).

However, we determined that the claimed invention was nevertheless unpatentable over the two remaining references, Balkan, which discloses treating strabismus by administering complexed botulinum toxin to humans, and Tse, which discloses that pure neurotoxin produces paralysis in rat muscles, and inhibits release of acetylcholine at the vertebrate neuromuscular junction, just like the corresponding complexed neurotoxin (*see id.* at 9). Therefore, we affirmed the rejection of claims 1, 2, 4, 5, 29, 47, and 63 as unpatentable over the combined teachings of Balkan and Tse.

REQUEST FOR REHEARING

Appellants request reconsideration of our decision affirming the Examiner's rejection of claims 1, 2, 4, 5, 29, 47, and 63 on the ground of obviousness.

Appellants contend that the Decision raised a new ground of rejection without designating it as such, and also misapprehended and overlooked certain matters of fact and law (Req. Reh'g 1), specifically Appellants' contention that the Schantz reference taught away from the claimed invention (*id.* at 8). Appellants request that the Board either reverse the obviousness rejection, or formally designate our affirmance a new ground of rejection and remand the application to the Examiner so that Appellants may have an opportunity to react to the thrust of the new rejection by submitting an amendment and/or a showing of additional facts or evidence (*id.* at 2).

DISCUSSION

Appellants acknowledge that relying on fewer references than the Examiner did in affirming an obviousness rejection, in and of itself, does not normally constitute a new ground of rejection (Req. Reh'g 3). However, Appellants contend that "the basic thrusts of the Board's rejection and the Examiner's rejection are different such that Appellant has not had a fair opportunity to respond to the thrust of the Board's rejection, thus the Board's 'affirmed' rejection constitutes a new ground of rejection" (*id.*).

Appellants contend that:

> The basic thrust of the Examiner's rejection is that Balk[a]n teaches the treatment of strabismus in humans using complexed botulinum toxin type A while the combination of Kohl, Tse, and Aoki '915 allegedly suggests, with the legally required reasonable expectation of success, that a person having ordinary skill in the art would substitute the purified neurotoxic component of botulinum toxin for the complexed botulinum toxin of Balk[a]n. Clearly, any rebuttal of this rejection directed, for example, toward the reasonable expectation of success of the suggested substitution allegedly provided by the combination of Kohl, Tse, and Aoki '915 must address the combination of the Kohl, Tse, and Aoki '915 teachings and not the teachings of any one of these references individually or in isolation.

(Req. Reh'g 3.)

> On the other hand, the basic thrust of the Board's rejection . . . is that Balk[a]n teaches the treatment of strabismus in humans using complexed botulinum toxin type A while Tse alone allegedly suggests, with the legally required reasonable expectation of success, that a person of ordinary skill in the art should substitute the purified neurotoxic component of a botulinum toxin for the complexed botulinum toxin of Balk[a]n.

(*Id.* at 4.)

Appellants argue that

> [T]he basic thrusts of the Board's rejection and the Examiner's rejection are fundamentally different in that the Board's rejection . . . requires an analysis of the prior art from the perspective of an ordinary skilled artisan as of December 28, 1993 . . . while the Examiner's rejection required an analysis of the prior art from the perspective of an ordinary skilled artisan as of May 21, 2003 . . . As such, Appellant has not had a fair opportunity to respond to the Board's new rejection based on Tse by itself with Balk[a]n from the perspective of an ordinary skilled artisan as of December 28, 1993.

(*Id.* at 5.)

At first blush, it is not readily apparent how an argument or evidence establishing the lack of a reasonable expectation of success based on the art available in 2003 would not have been equally applicable ten years earlier in 1993. However, the obviousness rejection in this case has the added complication of incorporating an enablement issue.

That is, the Examiner cited Schantz as evidence of lack of enablement as of the December 28, 1993 filing date of the parent '996 application (Ans. 4-8). Appellants, on the other hand, contended that in relying on Schantz, the Examiner "failed to consider the evidence as a whole, including the guidance and working examples in the '996 specification" (App. Br. 9), as supported by several articles addressed in the Smith[7] Declaration, some of which were published before the filing date of the '996 application (*id.* at 9, 11). Appellants discussed the prosecution history of the present application, and noted that in responding to a previous obviousness rejection, in discussing the Examiner's finding of lack of enablement, that "statements in

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[7] Declaration of Dr. Leonard A. Smith, dated November 20, 2007, and submitted December 20, 2007 under the provisions of 37 C.F.R. § 1.132.

Schantz teach away from the claimed invention" (App. Br. 12). We recognize that, in this context, an analysis of the state of the prior art, as a whole, from the perspective of the ordinary artisan in 1993 could be very different from an analysis from the perspective of the ordinary artisan in 2003. Moreover, we are mindful that the Examiner apparently informed Appellants that the obviousness rejection would be withdrawn if the claims were determined to be entitled to the priority date of the parent application.[8]

Therefore, in the interest of procedural fairness, we have modified our Decision to the extent that we designate our affirmance in the Decision entered May 21, 2010 a new ground of rejection. We decline to reverse the obviousness rejection on the basis of Appellants' argument that we only considered Schantz's relevance in terms of enablement, and did not consider its import as a teaching away, as that issue was not properly raised in the Appeal Brief.[9]

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[8] *See* Appellants' Interview Summary (p. 4, ¶ 3) submitted June 4, 2007, summarizing the substance of an interview conducted with the Examiner on May 23, 2007.

[9] Appellants point to page 12 of their Appeal Brief in arguing that we did not properly consider the relevance of Schantz as a teaching away. However, that portion of the Brief is essentially a partial summary of the prosecution history of this application, and merely states that in an earlier response dated September 26, 2006, "Appellants argued, in response to an obviousness rejection, that the statements in Schantz teach away from the claimed invention." Appellants have not pointed us to any discussion of the merits of Schantz as a teaching away which we overlooked or misapprehended.

TIME PERIOD FOR RESPONSE

This decision contains a new ground of rejection pursuant to 37 C.F.R. § 41.50(b) (effective September 13, 2004, 69 Fed. Reg. 49960 (August 12, 2004), 1286 Off. Gaz. Pat. Office 21 (September 7, 2004)). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review.

37 C.F.R. § 41.50(b) also provides that the appellant, WITHIN TWO MONTHS FROM THE DATE OF THE DECISION, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution.* Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner . . . .
>
> (2) *Request rehearing.* Request that the proceeding be reheard under § 41.52 by the Board upon the same record . . . .

GRANTED-IN-PART; 37 C.F.R. § 41.50(b)

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